



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/648,781 | 08/27/2003 | Youssef Bennani | ATI-0025 | 4487 |
| 34610 | 7590 | 04/05/2005 | EXAMINER | |
| FLESHNER & KIM, LLP P.O. BOX 221200 CHANTILLY, VA 20153 | | | HUANG, EVELYN MEI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/648,781 | Applicant(s) BENNANI ET AL. | |
| | Examiner Evelyn Huang | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8-15 and 121-136 is/are pending in the application.
- 4a) Of the above claim(s) 121-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3-5, 8-15, 121-136 are pending. Claims 2, 6, 7 have been canceled according to the amendment filed on 1-3-2005. Claims 121-136 have been withdrawn from further consideration as being drawn to the non-elected subject matter.

Election/Restrictions

2. Applicants maintain that the search and examination of Groups II to V would not be a serious burden to the examiner.

On the contrary, the inventions are distinct, each from the other because Inventions I and II-V are related as process of making and product made, and the product compound of Group I as claimed can be made by different materially different processes as described in the specification and in Groups II-V. A reference anticipating one group of invention would not render obvious the other groups of invention. The search is not co-extensive and is therefore burdensome. Since the search for one group of invention is not required for the other groups of invention, restriction as indicated is proper.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

Art Unit: 1625

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Duplicate Claims

4. The objection to Claims 2, 6, 7 under 37 CFR 1.75 as being a substantial duplicate of claims 1, 4, 5 respectively is rendered moot by the cancellation of claims 2, 6, 7.

Claim Rejections - 35 USC § 112

5. The rejection for Claims 1, 3-5, 8-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment and Applicants' Remarks.

Claim Rejections - 35 USC § 102

6. The rejection for Claims 1-3, 9, 15 under 35 U.S.C. 102(b) as being anticipated by Griffith et al (Bioorganic & Medicinal Chemistry Letters. 2002, 12 (4); 539-542) is withdrawn in view of the amendment excluding the prior art compound from the claims in a proviso, thereby setting a demarcation from Griffith's Compound 12 (page 541).

Claim Rejections - 35 USC § 103

7. The rejection for Claims 1, 3, 9, 15 under 35 U.S.C. 103(a) as being unpatentable over Joshi I (6376516, issued on 4-23-2002, is available as prior art under 102(b), PTO-1449, and is the US equivalent of WO 99/08528) or Joshi II (6673814, which is a CIP of 6376516) or Joshi (WO 99/08528, PTO-1449) is maintained for reasons of record.

Applicants maintain that the provisos have excluded the example compounds disclosed in Joshi. Although there may be some overlap between the broad genus of Joshi and the instant, there is no motivation and expectation of success for an obviousness rejection.

Contrary to Applicants' assertion that Joshi's genus is broad, it is a much narrower genus than the instant in that Joshi's compound has a hydrogen for instant G2 and G3, F for instant G1 and G4. D is either one of the 7 substituents in (i) (as in the instant (i)) or form a lactone or lactam with C (corresponding to instant E).

While Joshi's compounds wherein A and B form a nitrogen containing ring and D and E form a 5-membered lactone or lactam ring have been provisoed out in the instant, the instant claims still encompass compounds wherein D and E do not form a ring. These compounds are expressly taught by Joshi (column 3, definitions of C and D; columns 21-22, claims 5, 6) to be alternative optional choices to the lactone or lactam ring. Guided by Joshi's teaching, one of ordinary skill in the art would be motivated to modify Joshi's example compound by making the alternative compound wherein C and D do not form a ring to arrive at the instant invention, with the reasonable expectation of obtaining an additional neoplastic agent since Joshi had clearly taught that any species within the disclosed genus would be useful for treating a neoplastic disease.

Art Unit: 1625

8. The rejection for Claims 1, 3-5, 8-15 under 35 U.S.C. 103(a) as being unpatentable over Umezu (EP 201359, PTO-1449) is maintained for reasons of record.

The recitation of 'Joshi's example' is an inadvertent error. It should be 'Umezu's example'. A correction is hereby made. One of ordinary skill in the art would easily recognize such an error and ascertain the intended meaning from the context of the whole paragraph where Umezu's examples were recited. The rejection is reiterated as follows.

Umezu generically discloses a phthalide isoquinoline compound and the composition thereof for inhibiting the formation of lipid peroxides (page 10). Examples are described (page 15).

The last compound of page 18 has a =O on the benzofuranyl. The compound of instant claims 4, 6 has a =S on the benzofuranyl.

Umezu, however, teaches that the =O and =S are optional choices (page 10, definition of Y). An example of =S is found on page 18, second compound.

At the time of the invention, one of ordinary skill in the art would be motivated to modify Umezu's example compound by replacing =O with the alternative =S to arrive at the instant invention, with the reasonable expectation of obtaining an additional lipid peroxide formation inhibiting compound, since Umezu had clearly taught that any species within the small disclosed genus would be useful for inhibiting the formation of lipid peroxides.

The last compound of page 18 has an ethoxy on the benzene ring of the benzofuranyl. The instant compound has a halo or alkyl instead.

Umezu, however, teaches that halo, alkyl or alkoxy (such as ethoxy) are optional choices (page 10, definitions R1-R9). An example of the bromo substituent is found on page 17, third compound.

At the time of the invention, one of ordinary skill in the art would be motivated to modify Umezu's example compound by replacing the ethoxy with the alternative bromo to arrive at the instant invention, with the reasonable expectation of obtaining an additional lipid peroxide formation inhibiting compound, since Umezu had clearly taught that any species within the small disclosed genus would be useful for inhibiting the formation of lipid peroxides.

Art Unit: 1625

Applicants maintain that all the example compounds of Umezu have been excluded in the proviso. There is no clear motivation to select and choose a species to arrive at the instant invention.

On the contrary, there is only one difference between the instant and the prior art compound. More specifically, the compound of instant claims 4, 6 has a =S on the benzofuranyl whereas the last compound of page 18 of Umezu has a =O on the benzofuranyl. The last compound of page 18 of Umezu has an ethoxy on the benzene ring of the benzofuranyl. The instant compound has a halo or alkyl instead.

Umezu, however, expressly teaches that the =O and =S are optional choices (page 10, definition of Y). An example of =S is found on page 18, second compound. Umezu also teaches that halo, alkyl or alkoxy (such as ethoxy) are optional choices (page 10, definitions R1-R9). An example of the bromo substituent is found on page 17, third compound. Such express teachings of Umezu clearly motivate and guide the skilled in the art to modify the examples to arrive at the instant invention.

Double Patenting

9. The rejection for Claims 1, 3, 9, 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-6 of U.S. Patent No. 6376516 or claims 1-17 of US Patent No. 6673814 is withdrawn upon reconsideration in view of Applicants' Remarks that the patents and the instant application have no common inventors or assignee.

Claim Rejections - 35 USC § 112(1)

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1625

Claims 1, 3-5, 8-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The compound in the new proviso is not described in the specification.

Claim Rejections - 35 USC § 112(2)

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, it is unclear whether the claim is directed to a compound, or a mixture of salts, a mixture of solvates, a mixture of the solvated salts of formula I, or a mixture of compound of formula I, and its salts, solvates, and the solvated salts. It is recommended that the claim be amended to the singular/alternative format, e.g. A compound of formula I,a salt, a solvate, or a solvate of the salt thereof. The rejection is applicable to claims dependent on claim 1.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

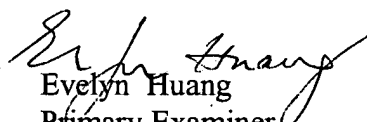
Art Unit: 1625

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625